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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/625,716 | 07/23/2003 | Stacia Linsky | 22310-RA | 8128 |

30184 7590 05/15/2006

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| EXAMINER |
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HALE, GLORIA M

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| ART UNIT | PAPER NUMBER |
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3765

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/625,716 | Applicant(s) LINSKY ET AL. | |
| | Examiner Gloria Hale | Art Unit 3765 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14, 16-23 and 25-29 is/are rejected.
- 7) ☒ Claim(s) 6, 15 and 24 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9-29-03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Fingleson et al (US 5,479,661).

In regard to claim 1 Fingleson et al discloses a breast self-examination apparatus, garment 10, including a form-fitting garment (since it fits a wearer's form as broadly claimed) with at least one examination pattern 38,40 (see Fingleson col. 3, lines 35-67 and col. 4, line 10) disposed on the garment wherein the garment is shirt-like and formed from a thin material(see col. 3, lines 1-4). The Fingleson apparatus comprises a low coefficient of friction since it allows the movement of the hands on the surface of the garment about the breasts with the examination pattern disposed on the garment so that it overlies a breast of the wearer as claimed in claims 3 and 4. (See Fingleson col. 3, line 35- col. 4, line 23). The Fingleson garment further comprises at least one alignment mark 42 centrally disposed within the examination pattern to center a wearer's nipple as claimed in claim 5 (See Fingleson col. 3, line 42). Fingleson discloses the pattern designs as claimed in claim 8 as seen in the figures. In regard to claim 28 Fingleson discloses the method of breast self-examination including obtaining the breast examination form-fitting garment 10 with the pattern thereon 38,40; putting

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on the garment, aligning the garment pattern with the breast and examining the breasts as claimed (see Fingleson col. 4, lines 10-23). (See Fingleson, figures 1 and 3-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 11-14, 16 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fingleson et al in view of Morrison (US 4,873,982).

Fingleson discloses the invention substantially as claimed. However, Fingleson does not specifically disclose the garment as extending to the underarm area. It is well known that the breasts, especially of large breasted women, extend to the underarm or side area. Women in addition to the lymph glands affected by breast cancer also extend into the underarm area. The Morrison garment is a breast examination garment that extends to an underarm or side area of the wearer and is also constructed of a material with the desired coefficient of friction for easy examination across the wearer's skin in addition to under the arms with the tube top structure of the garment. Morrison also discloses that the garment is adapted for use in other areas of the body where the detection of lumps is desired (such as the underarm area). (See Morrison, col. 4, lines 18-27). Also it is disclosed by Morrison that a doctor may mark the garment area where checking or examination is desired (See Morrison, col. 4, lines 12-17).

Accordingly, it would have been obvious to one having ordinary skill in the art to

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construct the Fingleson garment to extend under the arm areas and to mark those areas in a similar fashion as the Fingleson front surface as suggested by Morrison in col. 4, lines 12-17 in order to effectively examine the wearer for breast cancer. The Fingleson and Morrison garments are shirt-like and have the desired coefficient of friction as claimed in claims 12 and 13. Fingleson also discloses the central mark 42 with the examination patterns as in claims 14 and 16. (See Morrison, col. 4, lines 18-27, 12-17).

Claims 9, 10, 19-23, 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fingleson in view of Rusin (US 6,412,491).

Fingleson discloses the invention substantially as claimed. However, Fingleson does not specifically disclose the marker pens as claimed. Rusin discloses a breast examination device with a sheet material and a marker pen, col. 3, lines 32-34, not numbered in order to mark areas on the sheet 101 for further examination or areas of concern. Accordingly it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the garment of Fingleson to include a marking pen to mark areas on the garment over the sites on the wearer where further examination or areas of interest are on the wearer.

Claims 17, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fingleson et al in view of Morrison (US 4,873,982) and further in view of Rusin (US 6,412,491).

Fingleson et al and Morrison disclose the invention substantially as claimed. However, they do not specifically disclose the marking indicators as claimed. Rusin discloses a

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marking pen in col. 3, lines 32-34 that is used to mark area of interest or areas for further examination on the sheet material covering the wearer or patient. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the garment of Fingleson and Morrison to include a marking pen as disclosed by Rusin in order to mark areas on the garment over the sites where further examination or areas of interest are on the wearer.

Claims 6, 15 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

None of the cited references, alone or in combination, disclose the nipple aperture for nipple location on the garment as claimed in claims 6, 15 and 24.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gloria Hale whose telephone number is 571-272-4984. The examiner can normally be reached on Tues.-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on 571-272-4983. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gloria Hale
Primary Examiner
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